TITLE II—DRUG SAFETY

SEC. 201. REGISTRATION OF PRODUCERS OF DRUGS; APPLICABLE FEE.

(a) REGISTRATION.—

(1) EXPANDED APPLICABILITY.—Subsection (b) of section 510 is amended by adding at the end the following:

''(3)(A) The registration requirements of this section are deemed to apply to a person who owns or operates an establishment engaged in the manufacture, preparation, propagation, compounding, or processing of an active pharmaceutical ingredient of a drug or an excipient of a drug to the same extent and in the same manner as such requirements apply to a person who owns or operates an establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug.

''(B) For purposes of subparagraph (A), the term 'registration requirements' means—

''(i) the requirements of this subsection and subsections (c), (d), and (i);

''(ii) the requirements of subsection (h) (relating to inspection); and

''(iii) such other provisions of this section as the Secretary determines appropriate.''.

(2) MISBRANDING.—Paragraph (o) of section 502 (21 U.S.C. 352) is amended by striking ''in an establishment in any State not duly registered under section 510'' and inserting ''in an establishment not duly registered under section 510''.

(3) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) apply only with respect to registration under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) occurring on or after the later of—

(A) October 1, 2008; or

(B) the date of the enactment of this Act.

(b) REGISTRATION FEE.—

(1) MISBRANDING.—Paragraph (o) of section 502 (21 U.S.C. 352), as amended by subsection (a), is further amended by inserting after ''in an establishment not duly registered under section 510'' the following: ''or in violation of section 736C for failure to pay an annual registration fee''.

(2) ESTABLISHMENT.—Part 2 of subchapter C of chapter VII is amended by adding at the end the following:

"SEC. 736C. REGISTRATION FEE.

"(a) IN GENERAL.—Except as provided in subsection (b) of this section, the Secretary shall assess and collect an annual fee for registration under subsection (b), (c), (d), or (i) of section 510 for the purpose of defraying the costs of inspecting establishments registered under such subsection to ensure compliance by such establishments with the requirements of this Act relating to drugs.

"(b) EXCEPTIONS.—The Secretary shall not assess or collect a fee under this section for registration of an establishment under section 510 on the basis of such establishment's—

"(1) repackaging or otherwise changing the container, wrapper, or labeling of any drug; or

"(2) manufacture, preparation, propagation, or processing of an excipient of a drug.

"(c)(1) AMOUNT OF FEE.—The amount of a fee under this section shall be—

"(A) [____] for fiscal year 2009;

"(B) [____] for fiscal year 2010;

"(C) [____] for fiscal year 2011; and

"(D) [____] for fiscal year 2012.

[Note: Amounts will be calculated for purposes of subparagraphs (A) through (D) taking into consideration number of facilities, cost of facility inspection, appropriations base, rate of inspection, IT percent-

age cost for inspection, and the ratio of new resources to appropriated dollars.]

''(2) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2008, establish, for the next fiscal year, registration fees under subsection (a), based on the amount specified in paragraph (1) and any waiver, reduction, or adjustment under subsection (d) or (e).

''(d) FEE WAIVER OR REDUCTION.—

''(1) IN GENERAL.—The Secretary shall grant to a person a waiver from or a reduction of one or more fees under this section if the Secretary finds that—

''(A) such waiver or reduction is necessary to protect the public health;

''(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances; or

''(C) the applicant involved is a small business.

''(2) CONSIDERATIONS.—In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the

circumstances and assets of the applicant involved and any affiliate of the applicant.

''(3) SMALL BUSINESS DEFINITION.—In paragraph (1)(C), the term 'small business' means [to be supplied]

''(e) CREDITING AND AVAILABILITY OF FEES.—[to be supplied]

''(f) ANNUAL FISCAL REPORTS.—Beginning with fiscal year 2009, not later than 120 days after the end of each fiscal year for which fees are collected under this section, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(g) DEFINITION.—The term 'costs of inspecting' means the expenses incurred in connection with inspection described in subsection (a) for—

''(1) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, [advisory committees], and costs related to such officers, employees, [and committees] and to contracts with such contractors;

''(2) management of information, and the acquisition, maintenance, and repair of computer resources;

[''(3) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and**]**

''(4) collecting fees under this section and accounting for resources allocated for inspecting.''.

(3) EFFECTIVE DATE.—The Secretary of Health and Human Services shall first impose the fee established under section 736C of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (2), for fiscal years beginning with fiscal year 2009.

[(4) SUNSET DATE.—Section 736C of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (2), does not authorize the assessment or collection of a fee for registration under section 510 of such Act (21 U.S.C. 360) occurring after fiscal year 2012. **[**(Note: It is the policy that if this bill is not enacted on or before December 31, 2008, prior to enactment, this subsection will be revised to authorize fees through fiscal year 2017.**]]**

SEC. 202. INSPECTION OF PRODUCERS OF DRUGS AND ACTIVE PHARMACEUTICAL INGREDIENTS.

[(a) PROHIBITED ACT.—Subsection (p) of section 301 (21 U.S.C. 331), as amended by sections 101(a), is amended by inserting before ''or the failure to provide a notice required by section 510(j)(2)'' the following: ''the introduction or delivery for introduction into interstate commerce of any drug, any active pharmaceutical ingredient of a drug, or any excipient of a drug, before an initial inspection is complete in violation of section 510(h)(2),''.]

(b) INSPECTION.—Subsection (h) of section 510 (21 U.S.C. 351) is amended—

(1) by striking ''(h)'' and inserting ''(h)(1)'';

(2) by striking ''Every establishment in any State registered with the Secretary pursuant to this section'' and inserting ''Every establishment registered with the Secretary pursuant to subsection (b), (c), (d), or (i)'';

(3) by striking ''704(g), at least once'' and all that follows and inserting the following: ''704(g)—

''(A) at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter; or

''(B) at least once in the [4-year] period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive [4-year] period thereafter, if the Secretary [determines] information about the type of product produced in the establishment, inspection history, and compliance history exists to assess risk and to establish a risk-based inspection schedule.''.

(4) by adding at the end the following:

[''(2) Upon receipt of an initial registration under subsection (b), (c), (d), or (i) for an establishment, the Secretary shall ensure that such establishment is promptly inspected pursuant to section 704. Until such initial inspection is complete, any drug (including any active pharmaceutical ingredient of a drug) that is manufactured, prepared, propagated, compounded, or processed by such establishment shall not be introduced or delivered for introduction into interstate commerce. There shall be a new initial inspection of a drug establishment when the establishment begins to manufacture, prepare, propagate, compound, or process a drug or active pharmaceutical ingredient of a drug before its introduction or delivery into interstate commerce unless the product constitutes only a [minor] modification to a product previously manufac-

tured, prepared, propagated, compounded, or processed at the establishment.]

''(3) With respect to fiscal year 2009 and each subsequent fiscal year, the Secretary shall submit an annual report to the Congress on—

''(A) funding dedicated to inspections under this subsection; and

''(B) the number of establishments for which the frequency of such inspections has been modified pursuant to paragraph (1)(B).

''(4) For purposes of determining inspection frequency under subparagraphs (A) and (B) of paragraph (1), the Secretary shall establish information systems capacity sufficient to assess risk and shall develop and maintain a risk-based system for conducting surveillance of current good manufacturing practices by establishments registered with the Secretary pursuant to subsection (b), (c), (d), or (i). The Secretary shall have such capacity in place and begin implemention of such risk-based system not later than 3 years after the date of the enactment of the Food and Drug Administration Globalization Act of 2008. Such risk-based system shall include consideration of the class of the establishment's products and associated risks, the date the establishment was last inspected, the establishment's compliance and safety history, the estab-

lishment's shipping volume and history, and such other factors as the Secretary determines relevant to assessing the risk presented by the establishment.''.

(c) GAO REPORT.—Not later than 3 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit a report to the Congress on the risk-based process for conducting surveillance of current good manufacturing practices developed and implemented under section 510(h)(4) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b)(4) of this section.

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to drugs introduced or delivered for introduction into interstate commerce on or after the date that is 2 years after the date of the enactment of this Act.

(2) ESTABLISHMENTS ALREADY REGISTERED, BUT NOT INSPECTED.—In the case of any establishment that is registered under subsection (b), (c), (d), or (i) of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) as of the effective date specified in paragraph (1) but has not been inspected pursuant to section 704 of such Act (21

U.S.C. 374) as of such date, such amendments shall not apply until 2 years after such effective date.

(3) MODIFICATION OF INSPECTION FREQUENCY.—Notwithstanding paragraphs (1) and (2), the authority of the Secretary of Health and Human Services to modify inspection frequency under subparagraphs (A) and (B) of section 510(h)(1) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b)(3) of this section, shall take effect on the date of the enactment of this Act.

SEC. 203. DOCUMENTATION FOR ADMISSIBILITY OF DRUG IMPORTS.

Section 801 (21 U.S.C. 381), as amended by sections 112 and 122, is amended by adding at the end the following:

''(r) Beginning 3 years after the date of the enactment of this subsection, a drug shall not enter the United States unless the party offering the drug for import provides the Secretary, at the time of offering the drug for import, [information] demonstrating [compliance with applicable requirements pertaining to identity, strength, quality, purity, approval, listing, labeling, registration, and such additional categories as the Secretary, by guidance, determines are necessary for protection of the public health.] The Secretary may allow that such compliance

be demonstrated through verification by an accredited third party or through such other means as determined by the Secretary.''.

SEC. 204. DRUG SUPPLY QUALITY AND SAFETY.

[(a) ADULTERATION.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by adding at the end the following:]

[''(j) If it is drug that was manufactured, prepared, propagated, compounded, or processed by an establishment that [review timing: is or was at the time of such manufacture, preparation, propagation, compounding, or processing] in violation of section 505–2 because of—]

[''(1) the failure to have in effect and implement a quality risk management plan in accordance with section 505–2; or]

[''(2) the failure to provide an [electronic] statement requested by the Secretary under section 505–2(f).''.]

(b) QUALITY RISK MANAGEMENT PLANS.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505–1 the following:

''SEC. 505–2. DRUG SUPPLY QUALITY AND SAFETY.

''(a) IMPLEMENTATION OF QUALITY RISK MANAGEMENT PLAN.—An establishment required to be registered with the Secretary pursuant to subsection (b), (c), (d), or

(i) of section 510 for the manufacture, preparation, propagation, compounding, or processing of a drug shall have in effect and implement a quality risk management plan designed to ensure the safety and quality of each such drug, including any ingredients produced, manufactured, processed, packed, or held by another person.

''(b) PLAN PROVISIONS.—A quality risk management plan required by subsection (a) shall address risk assessment, risk control, risk communication, and risk review and shall—

''(1) provide for an assessment, prior to contracting with a person to supply raw materials or ingredients or to undertake any aspect of the manufacturing of the drug, of the suitability and competence of such person to carry out such activity, using audits, material evaluations, or qualification, as appropriate;

[''(2) define responsibilities and communication processes for manufacturing, quality control, and quality assurance activities of any person referred to in paragraph (1);**]**

[''(3) provide for the monitoring and review through periodic on-site audits of the facility conditions, controls, and practices of any person referred to in paragraph (1) and ensure the implementation

of appropriate measures to improve such conditions, controls, and practices;]

''(4) provide for the monitoring of incoming materials to ensure they are from a person that meets the requirements in paragraphs (1) through (3);

''(5) provide for implementation of effective systems, including appropriate specifications and test methods and verification of the drug ingredients' identity, quality, strength, and purity, to detect any hazard that has been, or is reasonably likely to be, present in or on the drug during production, manufacturing, processing, packing, holding, or transporting; and

''(6) be periodically revised and updated.

''(c) ADDITIONAL PROVISIONS.—If the Secretary determines that provisions in addition to those described in subsections (a) and (b) would be appropriate to include in a quality risk management plan for protection of the public health, including provisions for the prevention of intentional adulteration of a drug or class of drugs, the Secretary may by regulation require the inclusion of such provisions in a quality risk management plan.

''(d) APPLICATION OF SPECIFICATIONS OR TEST METHODS BY ORDER OF THE SECRETARY.—Upon a find-

ing that there is a significant threat to public health, the Secretary may order an establishment—

"(1) to promptly revise its quality risk management plan to include new or modified specifications or test methods for a drug; and

"(2) to promptly implement such specifications or test methods.

"(e) INSPECTION OF QUALITY RISK MANAGEMENT PLAN.—A quality risk management plan required by subsection (a) shall authorize the Secretary, in the course of an inspection of an establishment subject to this section or upon request by the Secretary, to conduct a review of the plan.

["(f) DOCUMENTATION OF SUPPLY CHAIN.—**]**

["(1) IN GENERAL.—**[**Each establishment required to be registered with the Secretary pursuant to subsection (b), (c), (d), or (i) of section 510 for the manufacture, preparation, propagation, compounding, or processing of a drug**]** shall provide to the Secretary, upon request, an **[**electronic**]** statement—**]**

["(A) identifying each prior sale, purchase, or trade of the drug, including each prior sale, purchase, or trade of its ingredients and raw materials; and**]**

[“(B) establishing that the drug [add: and, as applicable, its ingredients and raw materials] were manufactured, [add: prepared, propagated, compounded,] processed, distributed, shipped, warehoused, brokered, imported, and conveyed under conditions that ensure the identity, strength, quality, and purity of the drug.]

[“(2) CONTENTS.—The [electronic] statement required by paragraph (1) shall include—]

[“(A) the date of the [each such prior sale, purchase, or trade;]]

[“(B) the names and addresses of all parties to each such transaction; and]

[“(C) any other information required by the Secretary by regulation.”.]

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The requirements of sections [501(j)] and 505–2 of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), take effect 2 years after the date of the enactment of this Act.

(2) EXCEPTION.—Notwithstanding the effective date specified in paragraph (1)—

(A) the authority of the Secretary to order an establishment to promptly implement new or modified specifications or test methods for a drug, as described in section 505–2(d)(2) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), shall take effect on the date of the enactment of this Act;

(B) such authority shall apply irrespective of whether the establishment has in effect a quality risk management plan; and

(C) a civil penalty under section 303(h)(11) of the Federal Food, Drug, and Cosmetic Act, as added by section 211 of this Act, shall apply to a violation of an order under this paragraph to the same extent and in the same manner as such a penalty applies to a violation of an order under such section 505–2(d)(2).

SEC. 205. DELAY, LIMITATION OR DENIAL OF INSPECTION.

(a) PROHIBITED ACT.—Subsection (p) of section 301 (21 U.S.C. 331), as amended by sections 101(a) and 202(a), is amended by inserting before ''or the failure to provide a notice required by section 510(j)(2)'' the following: ''the delay, limitation, or denial of an inspection

under section 510(h), as determined by the Secretary under paragraph (5) of such section,''.

(b) REQUIREMENT.—Subsection (h) of section 510 (21 U.S.C. 351), as amended by section 202(b), is further amended by adding at the end the following:

''(5) An establishment registered with the Secretary pursuant to subsection (b), (c), (d), or (i) shall not delay, limit, or deny an inspection authorized by this subsection.''.

(c) DRUGS OFFERED FOR IMPORT.—The third sentence of subsection (a) of section 801 (21 U.S.C. 381), as amended by sections 112, 122, and 203, is amended by inserting ''or (4) such article has been manufactured, prepared, propagated, compounded, or processed by an establishment required to be registered with the Secretary pursuant to subsection (b), (c), (d), or (i) of section 510 and such establishment is in violation of section 510(h)(5) (prohibiting the delay, limitation, or denial of an inspection under section 510(h)),'' before ''then such article shall be refused admission''.

[SEC. 206. COUNTRY OF ORIGIN LABELING .]

[(a) MISBRANDING.—Section 502 (21 U.S.C. 352) is amended by adding at the end the following:**]**

[''(y) If it is a drug and—**]**

[''(1) its labeling fails to identify the country (or countries) which is the source of the active pharmaceutical ingredient in whole or in part and of its place of manufacture; or]

[''(2) the Website of the manufacturer of the drug does not list the country of origin for any drug ingredient of such drug.''.]

[(b) REGULATIONS.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall promulgate final regulations to carry out section 502(y) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).]

[(c) EFFECTIVE DATE.—The requirement of section 502(y) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), takes effect 2 years after the date of the enactment of this Act.]

SEC. 207. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.

(a) PROHIBITED ACTS.—Section 301(pp), as added by section 113(a), is amended—

(1) by striking ''423(a)'' and inserting ''423(a) or 568(a)'';

(2) by striking ''423(b)'' and inserting ''423(b) or 568(b)'';

(3) by striking ''423(c)'' and inserting ''423(c) or 568(c)''; and

(4) by striking ''423(d)(1)'' and inserting ''423(d)(1) or 568(d)(1)''.

(b) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.—Subchapter E of chapter V (21 U.S.C. 360bb et seq.) is amended by adding at the end the following:

''SEC. 568. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.

''(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

''(1) IN GENERAL.—A person (other than a household consumer or other individual who is the intended consumer of a drug) [who has a reason to believe that a drug intended for human use would cause serious, adverse health consequences or death] shall, as soon as practicable, notify the Secretary of the identity and location of the drug.

''(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Secretary may require by regulation.

''(b) RECALL AND CONSUMER NOTIFICATION.—

''(1) VOLUNTARY ACTIONS.—On receiving notification under subsection (a) or by other means of

a suspected adulteration or misbranding of a drug, if the Secretary finds that [there is a reasonable probability that a drug intended for human use would cause serious, adverse health consequences or death], the Secretary shall provide all persons (including the manufacturer, importer, distributor, or retailer of the drug) with an opportunity (as determined by the Secretary)—

''(A) to cease distribution of the drug;

''(B) to notify all entities—

''(i) that produce, manufacture, pack, process, prepare, treat, package, distribute, or hold the drug, to cease immediately those activities with respect to the drug; or

''(ii) to which the drug has been distributed, transported, or sold, to cease immediately distribution of the drug;

''(C) to recall the drug;

''(D) in consultation with the Secretary, to provide notice of the finding of the Secretary to all consumers to which the drug was, or may have been, distributed and to appropriate State and local health officials; and

''(E) to notify State and local public health officials.

''(2) MANDATORY ACTIONS.—If a person referred to in paragraph (1) does not carry out the actions described in that paragraph with respect to a drug within the time period and in the manner prescribed by the Secretary, the Secretary shall issue an order requiring such person—

''(A) to immediately cease distribution of the drug; and

''(B) to immediately notify health professionals and drug user facilities of the order and to instruct such professionals and facilities to cease use of such drug.

''(c) HEARINGS ON ORDERS.—The Secretary shall provide a person subject to an order under subsection (b)(2) with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on—

''(1) the actions required by the order; and

''(2) any reasons why the drug that is the subject of the order should not be recalled.

''(d) POST-HEARING RECALL ORDERS.—

''(1) AMENDMENT OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (c), the Secretary determines that an order under subsection (b)(2) with respect to a drug

should be amended to include a recall or other appropriate action, the Secretary shall, except as provided in paragraph (2)—

"(A) amend the order—

"(i) to require recall of the drug or other appropriate action; and

"(ii) to specify a timetable during which any such recall shall occur; and

"(B) require periodic reports to the Secretary describing the progress of any such recall.

"(2) CONTENTS OF ORDER.—

"(A) INDIVIDUALS AND DRUG USER FACILITIES.—An amended order under paragraph (1) shall not include—

"(i) a recall of a drug from individuals; or

"(ii) a recall of a drug from drug user facilities if the Secretary determines that the risk of recalling such drug from the facilities presents a greater health risk than the health risk of not recalling the drug from use.

"(B) NOTICE TO INDIVIDUALS SUBJECT TO RISKS.—An amended order under paragraph

(1) shall provide for notice to individuals subject to the risks associated with the use of such drug. In providing the notice required by this paragraph, the Secretary may use the assistance of health professionals who prescribed or dispensed such a drug for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705(b).

''(3) VACATION OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (c), the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

''(e) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.

[''(f) NON-DELEGATION.—The authority to issue or amend an order under subsection (b) or (d), respectively, may not be delegated to any official or employee other than the Commissioner of Food and Drugs, the Director of the Center for Drug Evaluation and Research, or the Director of the Center for Biologics Evaluation and Research, as appropriate.''.**]**

(c) EFFECTIVE DATE.—Sections 301(pp)(1) and 568(a) of the Federal Food, Drug, and Cosmetic Act, as amended and added by subsections (a) and (b), respectively, shall apply with respect to drugs as of such date, not later than 1 year after the date of the enactment of this Act, as the Secretary of Health and Human Services shall specify.

[SEC. 208. DESTRUCTION OF ADULTERATED, MISBRANDED OR COUNTERFEIT DRUGS OFFERED FOR IMPORT.]

[(a) IN GENERAL.—The fifth sentence of subsection (a) of section 801 (21 U.S.C. 381), as amended by sections 112, 122, 203, and 205, is amended by inserting before the period at the end the following: ", except that any product that is refused admission may, at the discretion of the Secretary, be destroyed and not exported if (1) it appears to pose a risk of injury or death, or (2) has a value of less than $2,000, as determined by the Secretary".]

[(b) DUE PROCESS PROTECTIONS.—[to be supplied]]

[(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act, regardless of when the product may have been refused admission.]

SEC. 209. ADMINISTRATIVE DETENTION OF DRUGS THAT APPEAR TO VIOLATE THE LAW.

(a) IN GENERAL.—Section 304(g) (21 U.S.C. 334(g)) is amended—

(1) by inserting ''drug or'' before ''device'' each place it appears; and

(2) in paragraph (1), by inserting after ''adulterated or misbranded'' the following: ''or, in the case of a drug, which in the determination of the officer or employee making the inspection appears to be in violation of section 505,''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on a date, specified by the Secretary of Health and Human Services, not later than 1 year after the date of the enactment of this Act.

[SEC. 210. PENALTIES REGARDING COUNTERFEIT DRUGS.

Section 303(a) (21 U.S.C. 333(a)) is amended by adding at the end the following paragraph:**]**

[''(3) Notwithstanding paragraph (1) or (2), any person who engages in any conduct described in section 301(i)(2) knowing that the conduct concerns the rendering of a drug as a counterfeit drug, or who engages in conduct described in section 301(i)(3) knowing that the conduct will cause a drug to be a counterfeit drug or knowing that a drug held, sold, or dispensed is a counterfeit drug, shall be fined in accordance with title 18, United States Code,

or imprisoned not more than 20 years, or both, except that if the use of the counterfeit drug by a consumer is the proximate cause of the death of the consumer, the term of imprisonment shall be any term of years or for life.''.]

SEC. 211. CIVIL MONEY PENALTIES FOR VIOLATIVE DRUGS AND DEVICES AND IMPROPER IMPORT ENTRY FILINGS.

[(a) IN GENERAL.—Section 303 (21 U.S.C. 333) is amended by adding at the end the following:]

[''(h)(1) Any person who violates section 301(a) shall be liable to the United States for a civil penalty not to exceed $____ per violation or, if the person knowingly committed the violation, $____ [per violation], not to exceed $____ for all such violations adjudicated in a single proceeding.]

[''(2) Any person who violates section 301(b) shall be liable to the United States for a civil penalty not to exceed $____ per violation or, if the person knowingly committed the violation, $____ [per violation], not to exceed $____ for all such violations adjudicated in a single proceeding.]

[''(3) Any person who violates section 301(c) shall be liable to the United States for a civil penalty not to exceed $____ per violation or, if the person knowingly committed the violation, $____ [per violation], not to ex-

ceed $____ for all such violations adjudicated in a single proceeding.**]**

["(4) Any person who violates section 301(d) shall be liable to the United States for a civil penalty not to exceed $____ per violation or, if the person knowingly committed the violation, $____ **[**per violation**]**, not to exceed $____ for all such violations adjudicated in a single proceeding.**]**

["(5) Any person who violates section 301(g) shall be liable to the United States for a civil penalty not to exceed $____ per violation or, if the person knowingly committed the violation, $____ **[**per violation**]**, not to exceed $____ for all such violations adjudicated in a single proceeding.**]**

["(6) Any person who violates section 301(i) shall be liable to the United States for a civil penalty not to exceed $250,000 per violation, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.**]**

["(7) Any person who violates section 301(k) shall be liable to the United States for a civil penalty not to exceed $____ per violation, not to exceed $____ for all such violations adjudicated in a single proceeding.**]**

["(8) Any person who violates section 301(p) by failing to register in accordance with section 510 shall be liable to the United States for a civil penalty not to exceed

$250,000 per each 30-day period of the violation, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding. The civil penalty authorized by this paragraph shall not apply if the person demonstrates substantial compliance with the registration requirements of section 510.**]**

[''(9) Any person who violates section 301(pp) by failing to notify the Secretary in violation of section 568(a) or by failing to comply with an order or an amended order issued under section 568(b) or 568(d)(1), respectively, shall be liable to the United States for a civil penalty not to exceed $250,000 per day, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.**]**

[''(10) Any person who violates **[**section 301(a)**]** by failing to have in effect and implement a quality risk management plan in accordance with section 505–2 shall be liable to the United States for a civil penalty not to exceed $15,000 per day, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.**]**

[''(11) In lieu of the civil penalty that would otherwise apply under paragraph (10), any person who violates **[**section 301(a)**]** by failing to have in effect and implement a new or modified specification or test method for a drug pursuant to section 505–2(d) shall be liable to the

United States for a civil penalty not to exceed $250,000 per day, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.]

[''(12) Any person who violates [section 301(a)] by failing to provide an electronic statement requested by the Secretary under section 505–2(f) shall be liable to the United States for a civil penalty not to exceed $15,000 per day, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.]

[''(13) The provisions of paragraphs (2), (5), (6), and (7) of subsection (g) shall apply to a civil money penalty under this subsection in the same manner as they apply to a civil money penalty under subsection (g)(1).''.]

[(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to violations occurring on or after the date of the enactment of this Act.]

SEC. 212. GENERIC FEE FOR PREAPPROVAL APPLICATIONS.

[to be supplied]

TITLE IV—MISCELLANEOUS

SEC. 402. UNIQUE IDENTIFICATION NUMBER FOR FOOD, DRUG, AND DEVICE FACILITIES AND ESTABLISHMENTS.

(a) FOOD AND COSMETICS.—Section 415(a)(3) (21 U.S.C. 350d(a)(3)) is amended by adding at the end the following: ''The registration number shall be the unique

identification number for each such facility.''. **[**more concise alternative: Section 415(a)(3) (21 U.S.C. 350d(a)(3)) is amended by inserting ''unique'' before ''registration number''.**]**

(b) DRUGS AND DEVICES.—Section 510(e) (21 U.S.C. 360(e)) is amended by adding after the first sentence the following: ''The registration number shall be the unique identification number for each such establishment.''.

(c) APPLICATION TO COSMETICS.—The amendment made by subsection (a) applies to cosmetics through the operation of section 604 of the Federal Food, Drug, and Cosmetic Act, as added by section 301(a).

(d) APPLICATION TO IMPORTERS.—See section 401(b) of this Act for the requirement for a unique identification number for importers that are registered.

(e) EFFECTIVE DATE.—The Secretary of Health and Human Services shall implement the amendments made by this section not later than 1 year after the date of the enactment of this Act.

[SEC. 408. SUBPOENA AUTHORITY.

Chapter III (21 U.S.C. 331 et seq.) is amended by adding at the end the following:**]**

[''SEC. 311. EXERCISE OF SUBPOENA AUTHORITY.]

[''(a) IN GENERAL.—For the purpose of—**]**

[“(1) any hearing, investigation, or other proceeding respecting a violation of this Act, or]

[“(2) any hearing, investigation, or other proceeding to determine if a person is in compliance with a standard or other requirement under this Act,]

[the Commissioner may issue subpoenas requiring the attendance and testimony of witnesses and the production of documentary evidence. Such attendance of witnesses and production of evidence at the designated place of such hearing, investigation, or other proceeding may be required from any place in the United States or in any territory or possession of the United States. Subpoenas of the Commissioner shall be served by a person authorized by the Commissioner by delivering a copy thereof to the person named therein or by certified mail addressed to such person at such person’s last known dwelling place or principal place of business. A verified return by the person so serving the subpoena setting forth the manner of service, or, in the case of service by certified mail, the return post office receipt therefor signed by the person so served, shall be proof of service. Witnesses so subpoenaed shall be paid the same fees and mileage as are paid witnesses in the district courts of the United States.]

[“(b) ENFORCEMENT.—In the case of a refusal to obey a subpoena duly served upon any person under subsection (a), any district court of the United States for the judicial district in which such person charged with refusal to obey is found, resides, or transacts business, upon application by the Commissioner, shall have jurisdiction to issue an order requiring such person to appear and give testimony or to appear and produce evidence, or both. The failure to obey such order of the court may be punished by the court as contempt thereof. Furthermore, the failure or refusal to obey such a subpoena shall be treated as a prohibited act under section 301(a).]

[“(c) RELATION TO OTHER PROVISIONS.—The subpoena authority vested in the Commissioner and the district courts of the United States by this section is in addition to any such authority vested in the Commissioner or such courts by other provisions of law.”.]

[SEC. 409. FDA BONUSES.

[to be supplied]]

[SEC. 410. EXTRATERRITORIALITY.

There is extraterritorial Federal jurisdiction over any violation of this Act relating to any food, drug, device, or cosmetic intended for import into the United States.]